

# **Emergency Declarations and the Law**

Jennifer M. Bruner, Staff Attorney  
Public Health Preparedness & Emergency Response  
Indiana State Department of Health

- (1) May allow officials to exercise special powers
- (2) May permit officials to suspend legal requirements

**Purpose of a declaration**

- (1) Identify types of declarations
- (2) Distinguish what actions may be triggered by each type of declaration
- (3) Recognize how public health & medical personnel may be affected

## Objectives

- (1) Declaration of general emergency
- (2) Declaration of disaster
- (3) Declaration of national emergency
- (4) Declaration of public health emergency

## **Federal declarations**

- More commonly follow a gubernatorial request
- May be declared when an incident involves federal property or responsibility
- Provides President with expansive powers

**Declaration of general emergency**

- For more extreme crises
- Grants expansive powers to President and other federal officials
- No Stafford Act declarations for H1N1

**Declaration of disaster**

- Unilaterally declared by the President
- Is a procedural device
- National Emergency declared for H1N1 on October 23, 2009

**Declaration of national emergency**

- Declared by the Secretary of DHHS
- No definition of “public health emergency”, so wide discretion
- Authorizes variety of actions to facilitate response

**Declaration of public health emergency**



- September 11th
- Hurricanes Katrina, Rita, Dean, Gustav, & Ike
- Severe flooding (IA & IN – June 2008)  
(ND & MN – March 2009)
- 56<sup>th</sup> Presidential Inauguration (Jan. 2009)
- 2009 H1N1 influenza

**PHE's declared by HHS Secretary**

- Waiving certain prescription and dispensing requirements
- Making temporary appointments of personnel
- Section 1135 waivers

**Actions following PHE declaration**

- Issued by the Food & Drug Administration
- Allows either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies

## **Emergency Use Authorizations**

- Antiviral Drugs:
    - Tamiflu (oseltamivir)
    - Relenza (zanamivir)
    - Peramivir IV
  - Devices:
    - N95 respirators
    - rRT-PCR Flu Panel (NPS, NS, TS, NPS/TS, NA)
    - rRT-PCR Swine Flu Panel (also referred to as Swine Flu Test Kit)
- CDC requested & FDA-issued EUA**

**Products**

- Two prerequisites
- Allows for waiver of certain Medicare, Medicaid, HIPAA and CHIP requirements (including a temporary waiver of EMTALA sanctions) under section 1135 of the Social Security Act

## **Section 1135 waivers**

- Step 1 – Secretary authorizes waiver
- Step 2 – Providers submit requests
- Step 3 – CMS reviews and validates
- Step 4 – Resume compliance with rules and regulations

## **Section 1135 waivers**

- Federal law (Public Readiness & Emergency Preparedness Act) enacted in 2005
- Authorizes Secretary of DHHS to issue declaration to provide tort liability immunity

**What is the PREP Act?**

A declaration includes the determination of a threat or credible risk, recommendation for action, and the category of diseases, health conditions or health threats. It also includes the effective time period, the covered population, the geographic area of administration, and any limitations.

**What is in a declaration?**



- *Manufacturers* of countermeasures;
- *Distributors* of countermeasures;
- *Program planners* of countermeasures;
- *Qualified persons* who prescribe, administer, or dispense countermeasures; and
- Officials, agents, and employees of any of these entities or persons are also covered persons.

**Who is covered?**

- Tort liability claims
- Not covered:
  - Willful misconduct
  - Other types of claims (ex. civil rights or labor law violations)

**What is covered?**

- DHHS establishing a Countermeasures Injury Compensation Program for H1N1 vaccines
- Compensation can include medical benefits, lost wages, and death benefits

**Countermeasures Injury Compensation Program**

April 30 – May 1, 2009

ISDH mobilizes and distributes antiviral medications received from the Strategic National Stockpile (SNS)

**Antiviral distribution**

- (1) Pharmacy / pharmacist dispensing
- (2) Practitioner dispensing
- (3) Local health department (practitioner dispensing)
- (4) Any healthcare facility (practitioner dispensing)

**Dispensing antiviral medications**

- First H1N1 vaccination in Indiana given October 5, 2009
- The million dollar question: Who can administer H1N1 vaccinations?

**H1N1 vaccine**

Physician's broad authority to delegate  
versus the Medical Licensing Board's  
interpretation of what is or is not  
appropriate

**The dilemma...**

- Injectable H1N1 vaccine – can administer to adults and those between 9 and 18 with parent/guardian consent & presence
- H1N1 nasal spray – can administer to adults and those between 2 and 18 with parent/guardian consent & presence

**Order by IN Board of Pharmacy**



- IDHS issued guidance on November 6, 2009
- ISDH provided additional instructional materials
- Provided local health departments with additional personnel resources to assist in administering H1N1 vaccinations

## **Paramedics and H1N1**

- Indiana has one type of declaration
- Definition of disaster includes laundry list of calamities that includes a “public health emergency”

**State definition of disaster**

- Nature of the disaster
- Specific area(s) affected/threatened
- Conditions that brought about the disaster or that make possible termination of the state of disaster emergency

**What's in the declaration?**

- Suspend regulatory statutes or rules
- Use all available resources of state government and political subdivisions
- Commandeer or use private property
- Allocate essential materials/services

**What can the governor do?**

Employ any measure and give any direction to the state department of health or local boards of health as is reasonably necessary for securing compliance with this chapter or with the findings or recommendations of the state department of health or local boards of health because of conditions arising from actual or threatened:

- (A) national security emergencies; or
- (B) manmade or natural disasters or emergencies.

**The governor may...**

- Protects individuals & facilities
- Providing services within scope of license
- In a location declared a disaster area  
(before or after the actual declaration)
- Absent gross negligence and willful misconduct

**Ind. Code § 34-30-13.5**

- Ind. Code § 10-14-3-29
- By principal executive officer of political subdivision
- Activates local response and recovery plans

**Local disaster declaration**

- Local disaster declaration is prerequisite
- Every IN county, city, town and township a party to the agreement
- Provisions for how requests for assistance may be made as well as reimbursement rates

## **Statewide mutual aid agreement**



- Cannot declare a public health emergency
- But may...
  - close schools
  - close churches
  - forbid public gatherings
  - isolate or quarantine

**What about the State Health Commissioner?**

Jennifer M. Bruner, Staff Attorney  
Public Health Preparedness & Emergency Response  
Indiana State Department of Health

Office: (317) 234-2818

E-mail: [jbruner@isdh.IN.gov](mailto:jbruner@isdh.IN.gov)

**Questions?**